STENT MANAGEMENT OF LEAKS AFTER BARIATRIC SURGERY: A SYSTEMATIC REVIEW AND META-ANALYSIS

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ABSTRACT

BACKGROUND

Despite the low rates of complications of bariatric surgery, gastrointestinal leaks are major adverse events that increase post-operative morbidity and mortality. Endoscopic treatment using self-expanding stents has been used in the therapeutic management of these complications with preliminary good results.

METHODS

We performed a systematic review and meta-analysis of self-expanding stents placement for the management of gastrointestinal leaks after obesity surgery. Overall proportion of successful leak closure, stent migration and reoperation were analysed as primary outcomes. Secondary outcomes were patients' clinical characteristics, duration and type of stent, other stent complications, and mortality.

RESULTS

A meta-analysis of studies reporting stents was performed, including 488 patients. The overall proportion of successful leak closure was 85.89 % (95% CI, 82.52- 89.25%), median interval between stent placement and its removal of 44 days. Stent migration was noted in 18.65 % (95% CI, 14.32-22.98%) and the overall proportion of re-operation was in 13.54 % (95% CI, 9.94-17.14%). The agreement between reviewers for the collected data gave a Cohen's κ value of 1.0. No deaths were caused directly by complications with the stent placement.

CONCLUSION

Endoscopic placement of self-expanding stents can be used, in selected patients, for the management of leaks after bariatric surgery with a high rate of effectiveness and low mortality rates. Nevertheless, reducing stent migration and re-operation rates represents an important challenge for future studies.

Keywords: Leak. Fistula. Endoscopic stent. Bariatric surgery.

INTRODUCTION

The number of bariatric/metabolic procedures performed worldwide in 2019 exceeded 833,000. Roux-en-Y gastric bypass (RYGB) and sleeve gastrectomy (SG) are the most widely used surgical techniques that offer the best results (35.3% and 47% of all operation records sumitted, respectively).[1-4] Overall, bariatric surgery has a low incidence of serious complications of approximately 4% and a mortality rate of 0.1%. Of all the complications, leaks are major adverse events that increase post-operative morbidity and mortality, especially in the acute phase.[5] The published incidence is around 0.1%-8.3% after RYGB and between 0.1%-7% after SG, with a decrease in recent years, mostly due to experience and the standardisation of the surgical technique. GI leaks outcome benchmarks of RYGB and SG are < 1.3 and <0.15, respectively, for primary bariatric surgery, and 3.5 % for elective secondary bariatric surgery of 3.5%.[6,7] Despite this decrease in the incidence, GI leak continues to be a major cause of morbimortality in patients undergoing bariatric surgery. [8-11]

The aetiology of this complication is diverse and multifactorial, although generally it is a question of mechanical or ischaemic causes, which involve excessive intraluminal pressure greater than the tensional force of the tissues and/or the staple line. The most common location of suture failure is the gastrojejunal suture after RYGB, and the proximal third of the staple line and the angle of Hiss after SG (85%) or at stapling in the antral region (15%).[5,8]

Leaks are classified according to the timing of clinical signs because of its impact on their management: early (within 2 weeks), intermediate (between 2 and 6 weeks) and late (after 6 weeks). In case of early leaks, an emergency reoperation was the mandatory, nowadays conservative treatment and endoscopic techniques are being used as an alternative treatment with successful results. Several studies agree that early and intermediate leaks diagnosis is established, more effective will be the nonoperative treatment, included stent placement.[12] Late leaks, especially leaks persisting more than four months despite a well-conducted conservative treatment, are considered as chronic and are very unlikely to heal without surgery.[13]

The therapeutic management of GI leaks includes both urgent re-operation of the patient and more conservative methods, such as absolute diet, enteral/parenteral nutrition support, antimicrobial therapy and adequate drainage of possible collections. Emergency surgical exploration and treatment after bariatric complications is currently a challenge for general surgeons, with heterogeneous results and a non-negligible associated morbidity and mortality. As a consequence of bariatric surgery, these patients are at risk of suffering multiple complications (thromboembolism, gastrointestinal leakage, intestinal occlusion, intestinal ischaemia, bleeding, etc.), and therefore may require admission to the ICU and prolonged hospital stays.[14]

In recent years, endoscopic treatment using self-expanding stents (SEMS), among other endoscopic techniques, has been used as a therapeutic management in the control of GI leaks after bariatric surgery, with satisfactory results, as recently published, in various studies. [15-20] The guidelines of the European Society of Gastrointestinal Endoscopy and the American Society for Metabolic and Bariatric Surgery, recommend stent placement for treating fistulas developing after bariatric surgery, in selected patients. [15-21] Meta-analyses and systemic reviews on this topic are limited .[10-12]

Several complicationts of the stent placement are described but no studies analysed the overall rates of rescue surgery after stent failure. The effectiveness of other endoscopic techniques such as clipping, and tissue sealants were the subject of previously published meta-analyses.[14-16]

Therefore, we carried out a systematic review and meta-analysis of SEMS placement for the management of GI leaks bariatric surgery. The aim of our study was to examine the safety and efficacy of the use of stents for the treatment of leakage after bariatric surgery, including all possible complications. In addition, we present our own experience in the use of endoprotheses (stents) for these complications, analyzing more than 1,000 laparoscopic bariatric surgeries in the last 19 years.

METHODS

Study design and literature search

A systematic review of the most relevant articles in recent years on the use of stents for the management of fistulas after bariatric surgery was performed, comparing our results with the described citations. This systematic review and meta-analysis was written following the guidelines of the PRISMA reports (Preferred Reporting Items for Systematic Reviews and Meta-Analyses),[22] and was registered in the international database PROSPERO (ID: 47115). The study was designed according to the MOOSE (Meta-Analysis of Observational Studies in Epidemiology).[23] Articles were searched in MEDLINE (PubMed), the Cochrane Library database, EMBASE (Ovid), and Database of Abstracts of Reviews of Effects (DARE), without restrictions. The search strategy consisted of various combinations of the terms "bariatric surgery", "bariatric surgery complications", "stent", "leak", and "fistula." The agreement between reviewers for the collected data was quantified by using Cohen's κ.[24]

Subsequently, we performed a retrospective observational study in the Bariatric and Metabolic Surgery Department of our hospital between January 2002 and October 2021. The database was searched for all patients who presented GI leak as a complication after undergoing bariatric surgery, treated with stent placement. This study was reviewed and approved by the institutional review board of our hospital and its ethics committee. Our observational study was included in the meta-analysis as an extra cohort.

Patients who were treated by surgical or medical management only, without SEMS placement, were excluded from our hospital study. The data collected were included: medical history number, age, sex, location, lenght of hospital stay, surgical technique performed, location and date of diagnosis of suture dehiscence (considering it an early complication if it occurred within the first 28 days postoperatively and a late complication if the lesion was identified after that time). We also recorded, the type of endoprosthetic material used, the occurrence of complications related to the endoprosthesis and the need for surgical reoperation. The antimicrobial therapy used, the administration of enteral or parenteral nutrition, the use of drains and the associated mortality were also included. The results obtained were compiled and processed using SPSS 3.1.1 software.

Definitions

Leak/fistula (GI leak): an endoscopic or radiologically confirmed dehiscence of anastomosis or leakage of gastrointestinal content from a surgical join between two hollow viscera or through a suture line around an organ.[25]
Successful leak closure by stenting: an endoscopic or radiologically confirmation of non-leakage after stent removal. This leak closure is attributable only to the stent placement and not to any subsequent surgery or other endoscopic treatment.
Stent migration: an endoscopic or radiologically confirmed stent found in a different location to the one where it was initially placed.
Reoperation: the necessity for surgical intervention to manage the fistula, after lack of leak closure with the stent management.
Failure to cure: surgery is needed after unsuccessful stenting.

Eligibility criteria

Studies were included in our systematic review if they met the following criteria: (1) original full-text articles that reported outcomes in the management of anastomotic leaks after obesity surgery with stents, (2) published in the last 15 years, (3) inlcluded all the following variables (a) proportion of correct leak closure by self-expandable stent, (b) proportion of stent migration, and (c) percentage of reoperation after unsuccessful stent management.The following studies were excluded: (1) duplicated studies, (2) studies without clear data and/or description of therapy are used; and (3) studies focusing on successful endoscopic methods for leak closure other than the stent placement.

Outcomes measures

The primary outcomes were proportion of correct leak closure by self-expandable stent, proportion of stent migration, and percentage of reoperation after unsuccessful stent management, in patients with stent placement in leak management after bariatric surgery. We considered stent management to be successful if it resulted in correct leak closure, independently of whether the stent migrated. We considered reoperation when the management of the leak with a stent was not been successful.
Secondary outcomes were patients' clinical characteristics, interval between stent placement and removal, type of stent, other stent complications and mortality.

Data extraction

Two investigators (A.M.H. and H.B.H) independently extracted data from all the included articles and created a data sheet. Study characteristics (author name, year of publication, type of study), data on the participants (sample size, age, gender); and data on interventions, success, and adverse events of stent therapy, were extracted. Furthermore, for each included study the same data were collected in our case series. Any disagreement between reviewers was solved by a third author.

Quality of evidence

Quality assessment of the included studies was assessed using the methodological quality and synthesis of case series and case reports described by Murad et al.[26] According to this tool, each study is judged on 4 broad perspectives: the selection of the study groups, the

ascertainment and the causality of the outcome observed, and the reporting of the case. The results of this tool were reported as an aggregate score (ranging from 0 to 8) as the sum of the scores of the eight binary responses. According to this tool, the average aggregate score across the studies was 5 (Supplementary Table 1).

Statistical analysis

A random-effects model described by DerSimonian and Laird was used to aggregate the study data.[27] Proportions of overall successful leak closure, stent migration and reoperation (rescue surgery) were given with 95% confidence intervals that are based on the exact binomial Clopper–Pearson method ($p<0.05$). This meta-analysis was performed by calculating pooled proportions of patients with study outcomes. Forest plots were drawn to show the point estimates in each study in relation to the summary pooled estimate. Statistical heterogeneity between the studies was evaluated with the Cochrane's Q statistics and the I^2 coefficients.[28] Therefore, a significance level of 0.1 was assumed, rejecting the null hypothesis that the studies are heterogeneous.[29] Some articles in order to consider studies with small-N case, a significance level of 0.1 was assumed to reject the null hypothesis. [18,23,29,30]

The publication risk of bias was examined by visual inspection of funnel plots and formally with Begg's test with continuity correction.[31] Sensitivity analysis excluded studies that deviated significantly from a logarithmic scale of the inverse standard error of the total study result, and studies where baseline values differed significantly from the overall average. The analysis was performed using the R Project for Statistical Computing, version 4.1.0 and the MATLAB-MathWorks, version R2018b (visual interpretation of funnel plot and sensitivity analysis).

RESULTS

Systematic review and meta-analysis

We carried out a systematic review of original articles that reported the use of stents for the treatment of leaks after bariatric surgery. The initial database search identified 1,941 reference articles, from which 21 relevant articles were selected and reviewed (22, including our descriptive study) [Fig. 1]. [32-52]

Table 1 shows the search results and the studies included in this meta-analysis, as well as the clinical variables of each of them. The agreement between reviewers for the collected data gave a Cohen's κ value of 1.0. The data focusing on the efficacy of self-expanding stents in the treatment of GI leaks after bariatric surgery were extracted from 22 studies (488 patients) that met the inclusion criteria. All the selected studies were published between 2005 and 2020.

The mean age of the patients was 41 years, with a mean BMI of 43.2 kg/m^2. In 16 of 22 studies, the majority of the patients were female. SG was the most common initial surgery, although also RYGB, duodenal switch (DS) and other bariatric techniques were also performed. Leaks were most often located at the gastroesophageal junction (angle of His). Only four studies provided data regarding the fistula size (<10mm). All the studies used covered stents (mainly fully covered stents) with a large size of 18-23 cm. These

stents were implanted using an endoscopic technique and monitored periodically by chest x-rays and endoscopic sessions.

Different complications associated with the procedure were reported. Reflux, pain and vomiting were the most common, while bleeding and perforation were the most severe. The interval between stent implantation and its removal varied between 26 and 150 days. The stent remained in place for a median duration of 44 days.

The primary outcomes are assessed in Fig. 2-4. For the analysis of each outcome, only studies with sufficiently homogeneous data were included, using the p-value resulting from Cochran's *Q*.

The overall proportion of successful leak closure was 85.89 % (95% CI, 82.52- 89.25%) (Fig. 2). The funnel plot, sensitivity analysis and the Begg's test suggested an existing bias and asymmetry between the studies (Supplementary Fig. 1). Therefore, five studies were excluded.[32,33,42,43,50] After excluding these studies, the remaining studies were homogenous (Cochran's Q p-value > 0.1, Q test value= 17.07, $\chi 2(15,0.10)=22.307$).

The overall proportion of stent migration was 18.65 % (95% CI, 14.32-22.98%) (Fig. 3). However, a significant heterogeneity between the studies was observed. The funnel plot, the sensitivity analysis, and the Begg's test suggested an existing bias and asymmetry. Therefore, eight studies, were located outside the funnel, were excluded.[32-34,36,41,42,45,50] In addition, three studies with no risk of bias were also excluded because of its heterogeneity.[35,40,43] (Supplementary Fig. 2). After excluding the above studies, the remaining studies appeared to be homogeneous (Cochran's Q p-value > 0.1, Q test value=7.9295, $\chi 2(8,0.10) = 13.362$).

The overall proportion of reoperation (rescue surgery after no leak closure with the stent management) was 13.54 % (95% CI, 9.94-17.14%) (Fig. 4). The funnel plot, the sensitivity analysis, and the Begg's test suggested an existing bias and asymmetry and significant heterogeneity between the studies was observed. Therefore, four studies were excluded.[32,33,42] In addition, three studies with no risk of bias were also excluded due to its heterogeneity.[33,46,50] (Supplementary Fig. 3). After excluding these seven studies, the remaining studies were homogeneous (Cochran's Q p-value > 0.1, Q test value=8.839, $\chi 2(14,0.10) = 21.064$), including a total of 342 patients.

Eight studies had reported deaths in their studies. [33,43,44,46,47,48,50,51] The overall mortality rate was 2.05% (10 out of 488 patients). Nevertheless, these events were not caused directly by endoscopic interventions but were the result of the patients' severe condition prior to endoscopic treatment.

Case reports – descriptive study

At the same time, we carried out a clinical review of 1,080 patients who had undergone bariatric surgery in our hospital from January 2002 to October 2020. The most frequently used surgical techniques were RYGB (598 operations, 55.4%) and SG (414 operations, 38.3%).

Although some postoperative complications (seroma, bleeding, trocar site infection, eventration, and several others) were observed during this period of time, only 22 patients

(2%) underwent urgent surgery due to any of them. Leakage was observed as a postoperative complication in 16 cases of these 22 cases (1.5% of the total). In our study, we reported 5 patients with gastrointestinal leak (0.46% of the patients studied) who were treated with stent placement. The other 11 cases underwent surgical treatment because of the leak size (more than 10mm), haemodynamically unstable or septic patients and associated complications as intra-abdominal abscesses. The main clinical characteristics of these patients and the results of stent placement are shown in Table 2 and Table 3.

The mean age of the patients was around 35.6 years (range 26-47 years), with a predominance of females (60%). Three patients had a Body Mass Index (BMI) of 40-49 kg/m^2 (range between 35 and 59 kg/m^2), with a mean of 44.2 kg/m^2. In four patients, the bariatric surgery technique used was SG. All the patients had been discharged from hospital without incident, in less than 72 hours after primary bariatric surgery.

Subsequently, the majority of the patients, presented abdominal pain, fever and elevation of acute phase reactants (APR) in the laboratory test on arrival at the Emergency Unit. All of these patients underwent a CT scan of the abdomen and pelvis with oral and intravenous contrast, which revealed a leak complication. Leakage was diagnosed early in 60% of the cases (between the 7th and 28th days after surgery), and in the remaining 40% it was diagnosed beyond the 28th postoperative day (late complication).

All the patients underwent a gastroscopy. In four patients, the leak size was <10mm. Leakage was located at the gastroesophageal junction (angle of Hiss) in SG, and at the gastrojejunal anastomosis in RYGB. After the diagnosis, all the patients in our series were treated by oral dietary rest, parenteral/enteral nutrition support and complementary antibiotic therapy. In addition, in three cases, initial urgent surgical treatment was performed, with review and drainage of the abdominal infection site using a laparoscopic technique.

All these patients underwent stent placement. However, the stent placement was deferred until 28 days after the diagnosis in four patients. In all cases, full-covered metal bariatric stents of a length of 18-24 cm were used. The interval between stent implantation and its removal was 42 days, with a median of 24 days (period range from 15 to 120 days).

Only in two cases stent migration occurred. In one of these cases, the migration occurred after the leakage was closed, but the patient required a surgical operation for its removal due to an intestinal occlusion at terminal ileum (Fig. 5). In the other case, the stent prosthesis was removed by endoscopy, after demonstrating its migration and absence of persistent gastric leakage by radiological control, after 18 days. In both patients, a fully covered metal endoprosthesis of 21cm length and 28mm diameter (Hanarostent®) had been placed.

The lenght of hospital stay exceded one month in all cases. Successful leak closure was observed in the 80% of the patients, after upper GI endoscopy. All the patients underwent this follow-up study before the stent was removed and one month after its removal to verify the absence of leakage. One patient (who underwent RYGB) presented a recurrence of the leakage two weeks after the stent removal. Surgical reoperation was needed to successfully close the leak. Table 4 shows the comparison between the results of our hospital's descriptive study and the data obtained in the meta-analysis.

DISCUSSION

In our systematic review, we reported the largest review of patients treated with stents for leak closure after bariatric surgery (n=488). We focused on the most commonly used endoscopic therapy for leak closure after bariatric surgery, SEMS. Such stents were used in all the studies included.

Although the development of GI leaks after bariatric surgery is rare (0.1-3%), it can be difficult to diagnose and treat and often results in significant morbidity and mortality.[52] Postoperative leaks continues to be a major cause of morbimortality in patients undergoing bariatric surgery. This complication is the second cause of death after RYGB, with a mortality rates ranging from 6% to 50%.[53-55]

Nonoperative treatment (oral rest, intravenous antibiotics, parenteral nutrition support and/or adequate percutaneous drainage) is essential for initially stabilising these patients, but is not always a definitive treatment. *Gonzalez et al.*[56] treated 36% of patients with leakage after bariatric surgery with medical therapy with a successful rate of 88%. *Ballesta et al.*[57] managed this complication conservatively in 60% of cases with a success rate of 97%.

Many of these patients require surgical reoperation for their resolution (haemodynamically unstable or septic patients, as well as patients with complicated leaks). *Ballesta et al.*[57] and *Carucci et al.*[58] reported percentages of 39% and 81% respectively. Revisional bariatric procedures carry a higher complication rate because of the added technical difficulty and patient comorbidity. Despite this, surgery remains the mainstay of definitive treatment for leaks in the post bariatric surgery period.

Nowadays, endoscopic treatment has been used as a therapeutic management in the control of GI leaks after bariatric surgery, with satisfactory results. There is a wide variation in the treatment of patients with postbariatric leaks because there is no definite consensus on the most appropriate therapeutic approach.

Despite recent studies had concluded that endoscopic clipping techniques, double pigtail drains and fibrin sealants are also effective for fistula closure in selected cases; their use in monotherapy is rare. Nevertheless, combined endoscopic techniques are opening up with a promising future. [49,59,60]

The over-the-scope clip (OTSC) provides more durable and full-thickness closure as compared with standard clips. *Haito-Chavez et al.*[61] reported in a multicenter retrospective study, successful closure rates of perforations (90%), leaks (73.3%) and fistulas (42.9%) in GI defects, with failure attributed to inflammatory or necrotic margins and larger perforations (>20 mm). Only in 28% of the patients as a result of bariatric surgery complication. *Bartell et al.*[62] reported in a recent systematic review, an overall rate of clinical success of 78.4% (55.8% for fistula; 72.6% for anastomotic leaks).

Also, *Rogalski et al*[20] reported in a systematic review, a successful closure rate of 67.1% and a few complications (migration, stenosis, tear); the 50% of the patients with therapy failure were referred for surgical repair. However, the authors mentioned that clip placement in the treatment of post-bariatric leaks is less effective as the leaks are surrounded by fibrotic and inflamed tissue and clips can act as a foreign body limiting

healing. Therefore, they preferred the use of stent as the first method, and clips when the leak persist after stent therapy.

Sealants which have been used to obliterate GI leaks include cyanoacryate and fibrin glue.[63,64] The most commonly used sealant for fistula closure is fibrin glue. It mechanically occludes the stomach wall defect and plays a predominant role in wound healing, forming matrix-building strands, which promote neovascularization and fibroblast proliferation.[64] *Rábago et al.* described complete sealing after post operative GI fistula with fibrin glue in 86.6% of the patients, with a mean 2.5 sessions (range: 1 to 5) and a mean healing time of 16 d (range 5-40 d).[63]

Clipping or fibrin glue related complications were also rare, although reported only by a few studies without adequate follow-up information. *Sehab et al.*[49] and *Haito-Chavez et al.*[60] reported a few complications associated with clipping such as anchor migration, tear, mediogastric stenosis. *Bartell et al.*[62] presented in systematic review, rates of bleeding in 2.7% of patients, superficial mucosal tearing in 1.4% of patients, and rescue surgery in the 15% of the patients after the application of the OTSC clip in GI fistulas. In the other hand, *Assalia et al.*[65] reported pain and fever in 12.5% of patients after fibrin glue application, and in most patients there was a need for multiple applications fo leak closure. However, any current study has analysed the impact of OTSC or tissue sealants in monotherapy for leak closure after bariatric surgery.

All the afore mentioned techniques have reported varying degrees of both technical and clinical success and adverse events, generating a lack of consensus compounded by the scantiness of randomized clinical trials that comparative evaluate these different treatment approaches.

Altought, the American Society for Metabolic and Bariatric Surgery position statement did not endorse one endoscopic modality over another[66], the most frequent techniques include endoscopic vacuum therapy (EVT) and endoscopic internal drainage which are applied based on a standardized algorithm.[67,68] Additionally, there are experimental reports on innovative approaches, as mesenchymal stem cells and platelet rich plasma therapy.[69]

Previous studies have proposed diferent management algorithms.[68,70,71] In patients whose condition is stable, with an acute leak without systemic inflammatory response syndrome or peritonitis, SEMS management is effective before the formation of an organized collection and over-the-scope clip (OTSC) had reported successful results, particularly for the management of early leaks after sleeve gastrectomy. For subacute or chronic leaks with an organized walled-off collection, internal drainage with 2 or more double-pigtail plastic stents is effective both clinically and from a cost perspective. Concurrent endoscopic necrosectomy can be performed, if feasible, to clean and remove necrotic infected material from within the cavity and enhance drainage. In the other hand, endoscopic vacuum therapy (EVT) may be a better approach in mediastinal collections because they are more difficult to manage.

Among the endoscopic treatments, stent placement has been gaining importance as an endoscopic technique for the management of complications after bariatric surgery, avoiding additional surgical intervention and minimising the associated morbidity and mortality. Although stenting is not currently the most used treatment and probably not

the most successful method, several studies have reported high success rates.[32-52] Stent placement reduces intraluminal pressure, which is considered to be the major cause of fistula occurrence and development. The exclusion of the fistula site reduces peritoneal contamination and accelerates the healing process.[72]

The primary outcomes recorded in this meta-analysis were proportion of correct leak closure by SEMS and proportion of stent migration. It also considered the percentage of reoperation after unsuccessful stent management, which has not been analysed in other meta-analyses. The effectiveness of the use of stents for leak closure after bariatric surgery has been demonstrated in several reviews. *Puli et al.*[18] and *Okazaki et al.*[19] reported an overall success rates of leak closure of 87.7% and 72.8%, respectively. In our meta-analysis, we recorded a proportion of 85.89%.

Despite the potential benefits of stent placement in managing fistulas, several complications associated with the procedure have been reported, such as reflux, chest pain, gastric ulcer, nausea or vomiting and migration. While pain (6-7%), ulcer (4%) and vomiting (11%) have relatively low incidence rates, stent migration (39%) is a major complication with a higher rate of occurrence.[49,58] Stents were fairly well tolerated in all evaluated studies in this systematic review and meta-analysis. Reported symptoms such as vomiting, reflux and pain were mild and transient, usually resolving within a few days. Perforation and bleeding complications were only reported in a few studies, with low incidence rates.

However, stent migration remains a challenge. *Okazaki et al.*[19] and *Rogalski et al.*[20] reported an overall migration rates of 27.1%-31.5% and 23%, respectively. In our meta-analysis we recorded a proportion of 18.65%, lower to the case series references.[73,74] Multiple studies have attempted to provide conclusions to reduce stent migration, such as the use of double pigtail catheters, anchorage devices and fixation materials, although more sophisticated trials to find a gold standard material are still needed. [49,75-79] It is possible that future designs of specific stents for bariatric surgery complications and experience in anchoring and placement may improve safety and efficacy in reducing the rate of migration and thus avoid other related complications.

No systematic reviews and meta-analyses had previously analysed the overall rates of rescue surgery after stent failure. In our meta-analysis we reported rates of 13.45% (2% for stent removal). We consider this to be an important complication associated with the use of stents, and encourage future studies to analyse it, in order to improve knowledge about the effectiveness of stents.

Our study had several limitations. Data extraction was the greatest challenge of this meta-analysis due to the high degree of heterogeneity among the studies. Some data regarding were not provided in all studies, such as fistula size and time interval between surgery, leak diagnosis and stent placement. Bariatric surgery complications were mixed while their management may differ significantly in reason of their different anatomy and physiology. Furthermore, we did not differentiate primary or secondary bariatric surgery complications. In secondary bariatric surgery the higher GI leak rate is not a consequence of more severe comorbidities, but is rather due to technical issues/tissue vascularization related factors. Most publications did not provide results of the effectiveness of closing leaks in relation to the stent used, and in many studies the use of endoscopic techniques

combined with stent placement was commonly observed without a detailed description. Therefore, we were unable to perform a separate analysis.

CONCLUSION

The results of our systematic review indicate that self-expanding stents can be used for the management of GI leaks after bariatric surgery with a high rate of effectiveness and a low mortality rates. Nevertheless, reintervention and stent migration represents a real problem with rates as high as 13.54% and 18.65 %, respectively. Therefore, more studies (probably, endoscopic combined methods) are still needed to establish a definitive basis for leak management after bariatric surgery and reduce migration rates. The results of our descriptive study are comparable to the data obtained in the meta-analysis and the remainder of studies published.

Compliance with ethical standards

Conflict of Interest: The authors declare that they have no conflict of interest.

Ethical Approval Statement: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent Statement: For this type of study formal consent is not required from all individual participants included in th study. Informed consent was obtained from the patient to publish these images.

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Table

Table 1. Studies assessing self-expanding stents in the treatment of post-bariatric leaks eligible for meta-analysis.

Study	Population (n)	Average age (years)	Gender	BMI, median (Kg/m^2)	Main surgical procedure	Localitation of fistula	Stent duration, median (days)	Reoperation poststent (%)	Stent migration (%)	Complications	Resolution of leak (%)	Mortality (%)	Stent type
Salinas. A 2006	17	35.6	Male (80%)	43.7	RYGB	Variable	60	6	6	-	94	0	Ultraflex
Eisendrath. P 2007	21	46	Female (72%)	41	SG / RYGB	Variable	71	9	4.7	Pain 30%, Stricture 9%	80	9	Ultraflex
Fukumoto. R 2007	4	38	Female (100%)	45	SG / RYGB	Variable	42	25	50	Vomiting 25%	75	0	Polyflex
Serra. C 2007	6	40.2	Female (66%)	44.3	SG / DS	Hiss angle	150	16	33	-	66	0	Hanarostent
Casella. G 2009	3	46.6	Male (66%)	56.5	SG	Hiss angle	55	0	33	-	100	0	Ultraflex
El Mourad 2012	47	41.2	Equal	42.5	SG	Hiss angle	44	13	15	Reflux, dysphagia, bleeding 2%	87	0	Ultraflex Polyflex
Marr. B 2012	4	44	Female (100%)	45	SG	Hiss angle	-	25	25	Pain 30% Vomiting 50%	75	0	Wallflex
Simon F. 2013	9	42	Female (88%)	44	SG	Hiss angle	43	22	11	-	78	0	Hanarostent
Leenders J.M 2013	11	41	Female (82%)	-	SG	Hiss angle	105	10	18	-	90	0	Polyflex
Alazmi. W 2014	17	34	Male (54%)	43	SG	Hiss angle	44	12	6	Dysphagia 18%, bleeding 12%	76	0	Ultraflex
Galloro. G 2014	4	47	Equal	51.5	SG	Hiss angle	56	0	25	Pain 30% Vomiting 50%	100	0	Megastent
Fishman. S 2015	26	42	Female (81%)	41	SG	Hiss angle	26	7.7	27	Vomiting 5% Bleeding 3%	65	3	Wallflex
Périssé. L 2015	29	36.7	Female (60%)	44	SG / RYGB	Variable	63	13.7	24	Vomiting 5% Bleeding 3%	86	3.4	Full covered Stent
van Wezenbeek 2015	12	43	Female (70%)	47	SG	Hiss angle	27	17	66	Perforation 40%	75	0	Hanarostent
Almadi. M 2017	64	36	Male (55%)	40	SG	Hiss angle	49	3	10.4	Pain 56% Vomiting 11%	93.7	3	Wallflex Ultraflex
Klimczak. T 2017	13	42	Female (66%)	45.7	SG	Hiss angle	32	30	46	Perforation 7%	84	7.6	Megastent
Martín del Campo 2017	24	45	Female (70%)	-	SG	Hiss angle	30	24	30	Vomiting 12%	80	4	Wallflex
Shehab. H 2017	62	34	Female (66%)	48	SG	Hiss angle	42	11	18	Bleeding 6%	82	0	MegaStent
Boerlage. T 2018	38	45.4	Female (58%)	43	SG / RYGB	Variable	28	5.3	12	Stricture and bleeding 2%	66	2.6	Beta
Krishnan. V 2019	37	40.5	Female (70%)	45	SG	Hiss angle	44	16	27	Reflux 41%	83	2	Endomaxx
Shyam. V 2019	35	47.6	Female (88%)	36	SG	Hiss angle	30	5.7	20	Obstruction 5%, Vomiting 5%	94.3	0	Wallflex
Martínez. A 2021	5	35.6	Female (60%)	44	SG	Hiss angle	42	20	40	Reflux 40%, Vomiting 20%	80	0	Hanarostent

* SG, Sleeve Gastrectomy; DS, Duodenal Switch; RYGB, Gastric Bypass.

Table 2. Characteristics of the patients included in our descriptive study (n= 1,080).

Age (years)	35.6[a]
Sex	
Male	2 (40)
Female	3 (60)
BMI (kg/m^2)	
≤ 30	0 (0)
31-39	1 (20)
40-49	3 (60)
≥50	1 (20)
Type of surgery	
SG	4 (80)
RYGB	1 (20)
Presentation	
Abdominal sepsis (fever, pain, rising APR)	4 (80)
Parapneumonic pleural effusion	1 (20)
Time to diagnosis (days)	
7-28	3 (60)
>28	2 (40)
Initial treatment before stent placement	
Surgical drain	3 (60)
Conservative treatment	2 (40)
Time to stent placement (days)	
7-28	1 (20)
>28	4 (80)
Length of hospital stay after leakage diagnosis (days)	
31-60	2 (40)
>61	3 (60)
Stent duration (days)	
15-30	3 (60)
31-60	1 (20)
>61	1 (20)

*Categorical data are presented as a number (percentage)

[a] Median (years)

Table 3. Endoscopic characteristics and outcomes recorded in our descriptive study.

Leak site	
Angle of His	4 (80)
Gastrojejunostomy	1 (20)
Leak size (mm)	
<10	4 (80)
≥10	1 (20)
Complications	
Mild intolerance	3 (60)
Migration	2 (40)
Successful leak closure (days)	
< 30	3 (60)
≥ 30	1 (20)
Reoperation	1 (20)

*Categorical data are presented as a number (percentage)

Table 4. Comparison between our hospital's descriptive study results and the meta-analysis carried out.

Study	Population (n)	Average age (years)	Gender	BMI, median (Kg/m^2)	Main surgical procedure	Localitation of fistula	Stent duration, median (days)	Resolution of leak (%)	Stent migration (%)	Reoperation poststent (%)	Stent type
Cases report	5	35.6	Female	44	SG	Hiss angle	42	80	40	20	Full covered Stent
Meta-analysis	483	41	Female	43.2	SG	Hiss angle	51.6	85.96	18.65	13.45	Full covered Stent

Figure

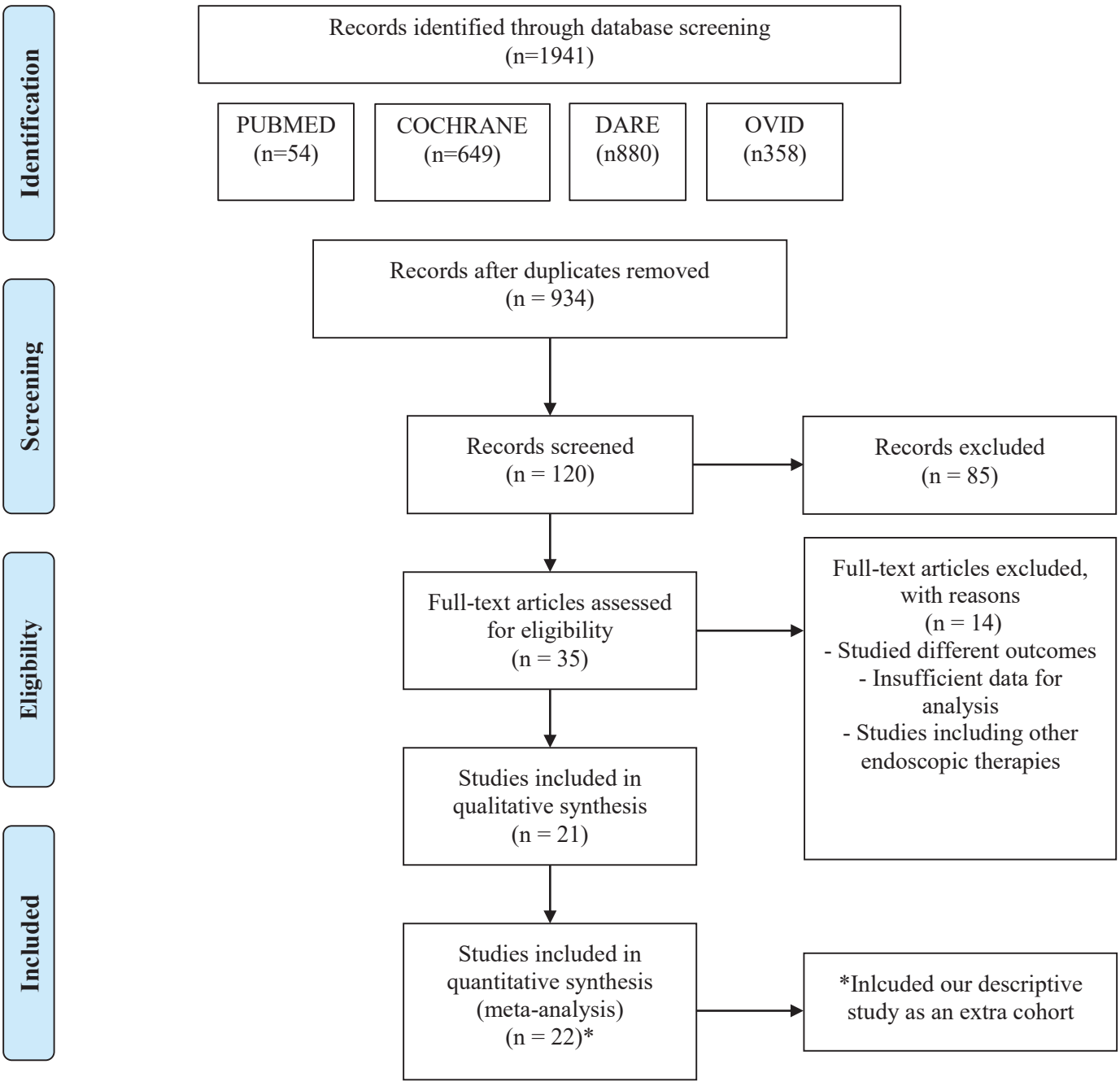


Figure 1. Flowchart for search strategy and selection of eligible studies for systematic review and meta-analysis.

Study	Events	Total	Weight	Proportion (95% CI)
Salinas et al.	16	17	4.14%	94.12% (82.93, 105.30)
Eisendrath et al.	17	21	5.11%	80.95% (64.16, 97.75)
Fukumoto et al.	3	4	0.97%	75.00% (32.56, 117.44)
El Mourad et al.	41	47	11.44%	87.23% (77.69, 96.77)
Marr et al.	3	4	0.97%	75.00% (32.56, 117.44)
Simon et al.	7	9	2.19%	77.78% (50.62, 104.94)
Leenders et al.	10	11	2.68%	90.91% (73.92, 107.90)
Alazmi et al.	13	17	4.14%	76.47% (56.31, 96.63)
Périssé et al.	25	29	7.05%	86.21% (73.66, 98.76)
van Wezenbeek et al.	9	12	2.92%	75.00% (50.50, 99.50)
Almadi et al.	60	64	15.57%	93.75% (87.82, 99.68)
Klimczak et al.	11	13	3.16	84.62% (65.00, 104.23)
Martin del Campo et al.	19	24	5.84	79.17% (62.92, 95.41)
Sehab et al.	51	62	15.05	82.26% (72.75, 91.77)
Krishnan et al.	31	37	9.00	83.78% (71.91, 95.66)
Vedantam et al.	33	35	8.51	94.29% (86.60, 101.98)
Martínez et al.	4	5	1.22	80.00% (44.94, 115.06)
(Q test, p-value > 0.1)	**353**	**411**	**100%**	**Pooled proportion (95% CI) 85.89% (82.52, 89.25)**

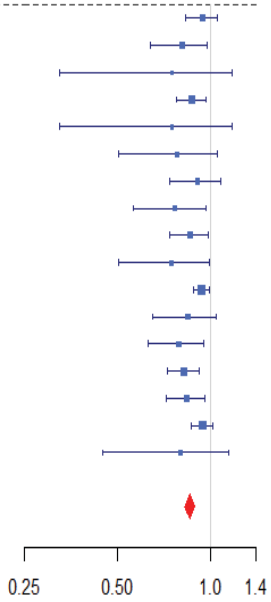


Figure 2. Forest plot for successful leak closure.

Study	Events	Total	Weight	Proportion (95% CI)
El Mourad et al.	7	47	15.11%	14.89% (4.72, 25.07)
Marr et al.	1	4	1.28%	25.00% (-17.44, 67.44)
Simon et al.	1	9	2.89%	11.11% (-9.42, 31.64)
Périssé et al.	7	29	9.33%	24.14% (8.56, 39.71)
Almadi et al.	7	64	20.58%	10.94% (3.29, 18.58)
Martin del Campo et al.	7	24	7.72%	29.17% (10.98, 47.35)
Sehab et al.	11	62	19.94%	17.74% (8.23, 27.25)
Krishnan et al.	10	37	11.90%	27.03% (12.72, 41.34)
Vedantam et al.	7	35	11.25%	20.00% (6.75, 33.25)
(Q test, p-value > 0.1)	**58**	**311**	**100%**	**Pooled proportion (95% CI) 18.65% (14.32, 22.98)**

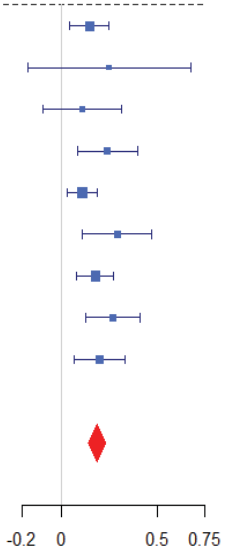


Figure 3. Forest plot for stent migration.

Study	Events	Total	Weight	Proportion (95% CI)
Salinas et al.	1	17	4.90%	5.88% (-5.30, 17.07)
Eisendrath et al.	2	21	6.05%	9.52% (-3.03, 22.08)
Fukumoto et al.	1	4	1.15%	25.00% (-17.44, 67.44)
El Mourad et al.	5	47	13.54%	10.64% (1.82, 19.45)
Marr et al.	1	4	1.15%	25.00% (-17.44, 67.44)
Simon et al.	2	9	2.59%	22.22% (-4.94, 49.38)
Leenders et al.	2	11	3.17%	18.18% (-4.61, 40.97)
Alazmi et al.	2	17	4.90%	11.76% (-3.55, 27.08)
Périssé et al.	4	29	8.36%	13.79% (1.24, 26.34)
van Wezenbeek et al.	2	12	3.46	16.67% (-4.42, 37.75)
Klimczak et al.	3	13	3.75	23.08% (0.17, 45.98)
Martin del Campo et al.	5	24	6.91	20.83% (4.59, 37.08)
Sehab et al.	8	62	17.87	12.90 % (4.56, 21.25)
Krishnan et al.	6	37	10.66	16.22% (4.34, 28.09)
Vedantam et al.	2	35	10.09	5.71% (-1.98, 13.40)
Martínez et al.	1	5	1.44	20.00% (-15.06, 55.06)
(Q test, p-value > 0.1)	**47**	**347**	**100%**	**Pooled proportion (95% CI) 13.54% (9.94,17.15)**

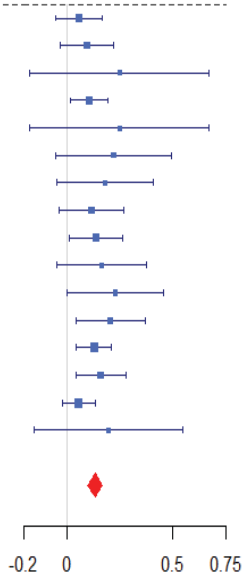


Figure 4. Forest plot for re-operation (rescue surgery).

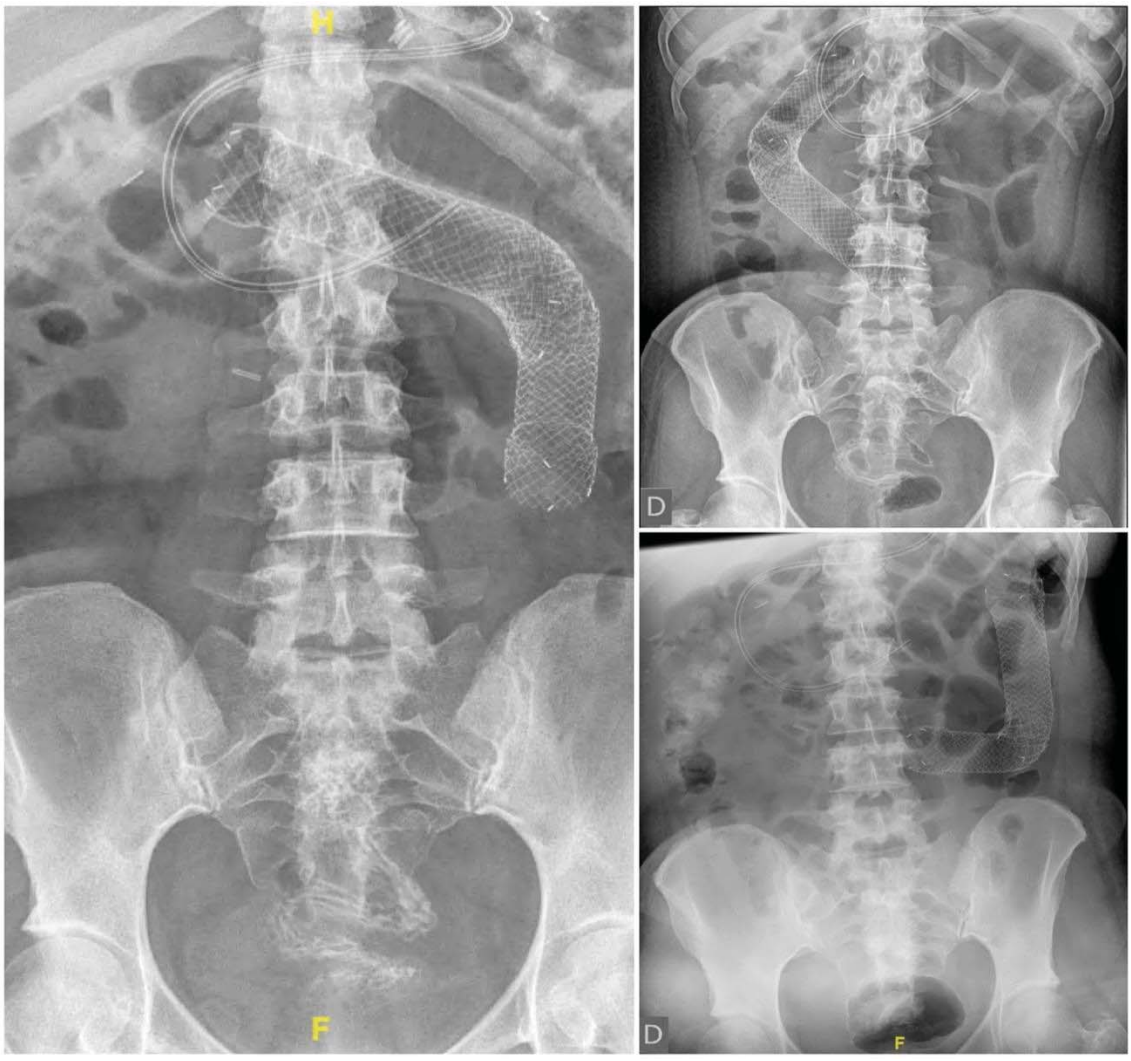
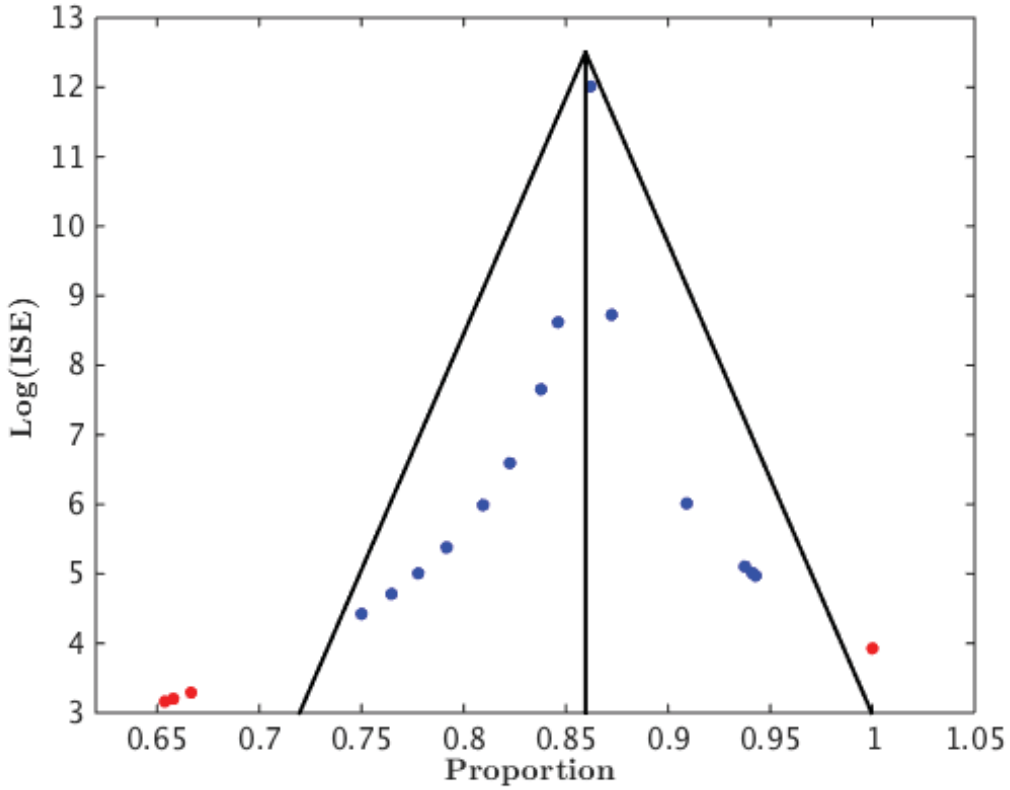


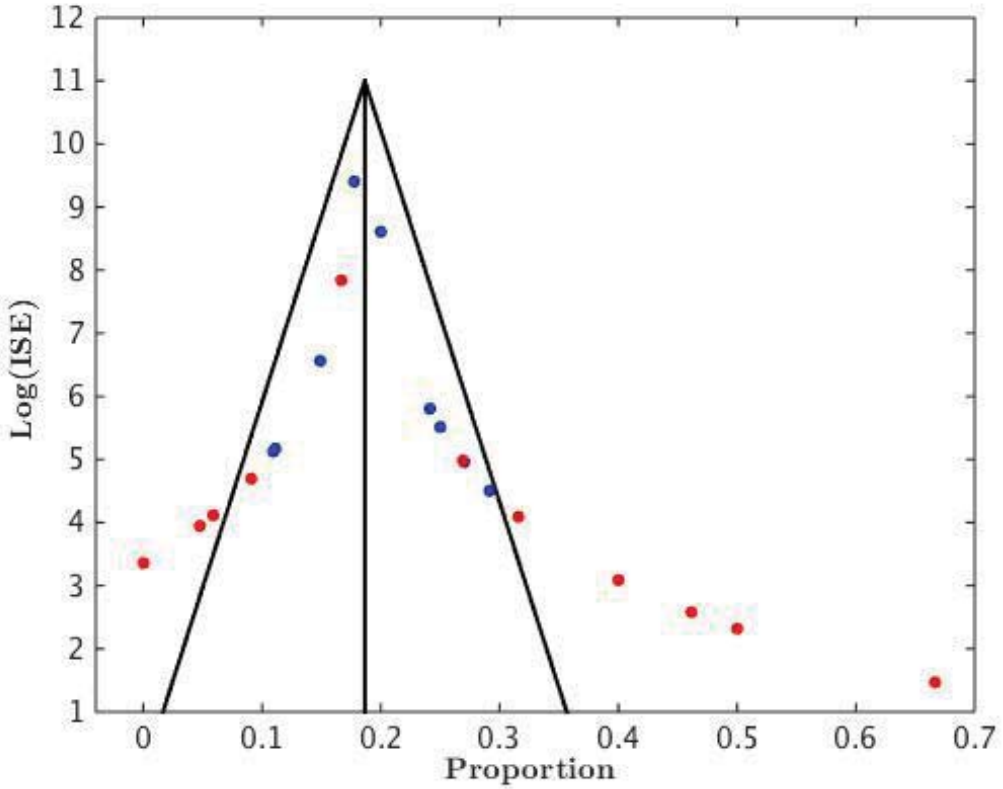
Figure 5. Stent migration. Radiological findings.

Supplementary Table 1. Grading of the certainty of evidence. Evaluation of risk of bias in the selection, ascertainment, causality, and reporting domains across the studies according to PRISMA.

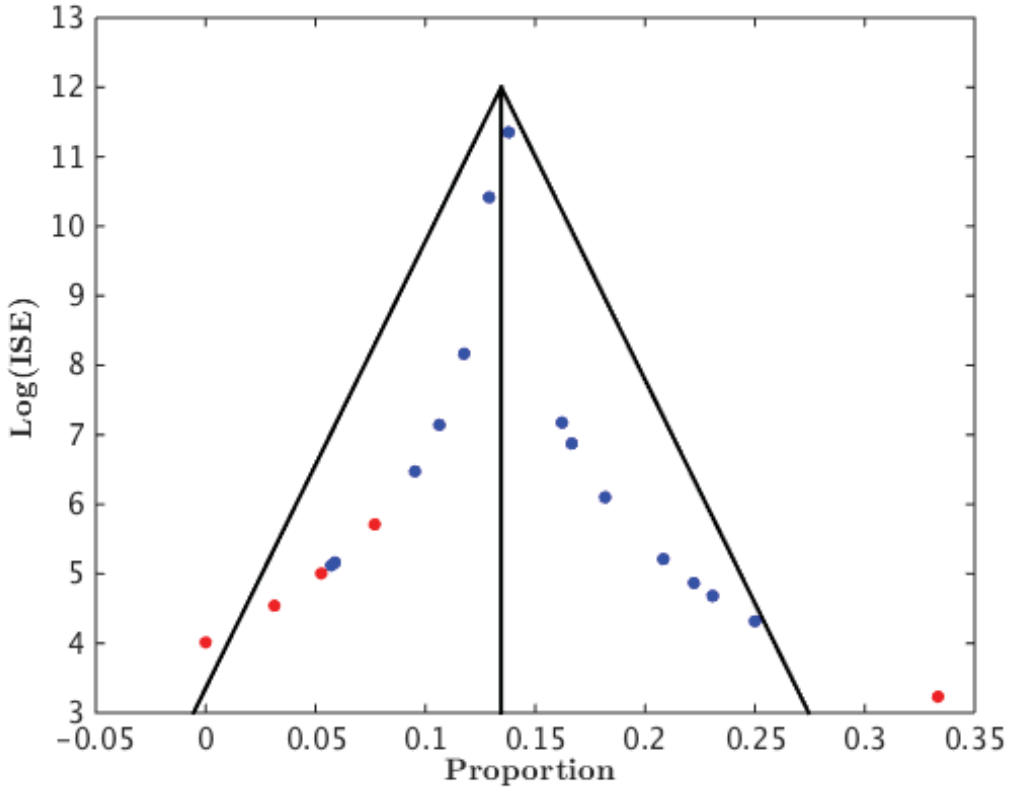
Domain	Selection	Ascertainment		Causality				Reporting	Total
References	Does the patient(s) represent(s) the whole experience of the investigator (centre) or is the selection method unclear to the extent that other patients with similar presentation may not have been reported?	Was the exposure adequately ascertained?	Was the outcome adequately ascertained?	Were other alternative causes that may explain the observation ruled out?	Was there a challenge/ rechallenge phenomenon ?	Was there a dose–response effect?	Was follow-up long enough for outcomes to occur?	Is the case(s) described with sufficient details to allow other investigators to replicate the research or to allow practitioners make inferences related to their own practice?	
***Salinas. A* et al.**	1	1	1	1	0	0	1	1	6
***Eisendrath. P* et al**	0	1	1	0	0	0	1	1	4
***Fukumoto. R* et al**	0	1	1	1	0	0	0	1	4
***Serra. C* et al.**	0	1	1	0	0	0	0	1	3
***Casella. G* et al**	1	1	1	0		0	1	1	5
***El Mourad* et al**	**1**	**1**	**1**	**0**	**0**	**0**	**1**	**1**	**5**
***Marr. B* et al**	0	1	1	0	0	0	1	0	3
***Simon F* et al**	1	1	1	0	0	0	1	1	5
***Leenders J.M* et al**	1	1	1	0	0	0	1	1	5
***Alazmi. W* et al**	1	1	1	0	0	0	1	1	5
***Galloro. G et* al**	0	1	1	0	0	0	1	1	4
Fishman. S et al.	1	1	1	0	0	0	1	1	5
***Périssé. L* et al.**	1	1	1	0	0	0	1	1	5
***van Wezenbeek* et al.**	1	1	1	0	0	0	1	1	5
***Almadi. M* et al**	1	1	1	1	0	0	1	1	6
***Klimczak. T* et al.**	1	1	1	1	0	0	1	1	6
***Martín del Campo* et al.**	1	1	1	0	0	0	1	1	5
***Shehab. H et* al.**	1	1	1	1	0	0	1	1	6
***Boerlage. T* et al.**	1	1	1	1	0	0	1	1	6
***Krishnan. V* et al.**	1	1	1	1	0	0	1	1	6
***Shyam. V* et al**	1	1	1	1	0	0	1	1	6
***Martínez A.* et al**	1	1	1	1	0	0	1	1	6



Supplementary Fig. 1. Funnel plot, sensitivity analysis, and Begg's test result for successful leak closure.



Supplementary Fig. 2. Funnel plot, sensitivity analysis, and Begg's test result for stent migration.



Supplementary Fig. 3. Funnel plot, sensitivity analysis, and Begg's test result for re-operation.